Statement of the Honorable
Billy Tauzin, Chairman
Subcommittee on Telecommunications,
Trade, and Consumer Protection
Hearing on Whether our Legal System is Jeopardizing Consumers' Access to Life-Saving Products

April 8, 1997

Imagine that you or one of your loved ones suddenly develops bone cancer and needs a replacement joint. Or that your newborn child is born with a life-threatening condition, shared by 70,000 others, called hydro-ceph-a-lus, requiring a brain shunt to drain excess internal fluid build-up. Further imagine that you rush to the hospital to save your loved one, only to find that the quality medical devices that would save you or your child are no longer available in this country.

This is not merely some consumer nightmare. It is the future reality facing two of our witnesses here today.

More than 8 million Americans rely on life-saving or life-enhancing implanted medical devices. And yet, Dr. Aronoff will be testifying before us today on a major study his firm has completed which found that only 25% ___ .just 25% ... of biomaterials companies are currently willing to supply implant manufacturers, because of our out-of-control legal system.

For example. Polyester yarn is used for numerous implants such as heart valves, helping to save the lives of tens of thousands of Americans each year. Tragically, independent heart valve manufacturers are no longer available to purchase this supply from any source. That means that once these companies use up their remaining supplies in the next couple of years, Americans with heart problems will have to travel overseas for proper treatment. Poly-tetra-flouro-ethylene, or PTFE, which is used in a wide variety of implants such as ventilation tubes for infants, is only being sold in limited forms to select, financially powerful companies that can indemnify suppliers against any liability risk.

Polyacetal resins, which are used for cancer therapy, are no longer being produced. Some patients hold out hope that the only two producers of this resin might be convinced, for humanitarian reasons, to recontinue their supplies despite

potential financial losses, If not, once medical device manufacturers use up their remaining stockpiles of resin, American consumers will suffer.

In two to three years from now, when the supplies of silicone for implantable medical devices runs out, where is little Titus Simonini going to get a replacement brain shunt? When the stockpiles of polyurethane are gone, where is Rita Bergman going to get her replacement knee joints?

We also have before us Dr. Karen Hicks, who has suffered terrible tragedies from a medical device gone wrong, the Dalkon Shield. Dalkon Shield was manufactured and marketed before Congress enacted the Medical Device Amendments of 1976, which regulated such medical devices for the first time. I feel great compassion for Ms. Hicks, and fully support her right and the rights of others who have been injured by negligent and wrongful manufacturers to recover reasonable compensation for all injuries. However, that does not lessen the issue we're focusing on today of consumers' access to biomaterials supplies. Even the so-called FDA defense, which I hope will be the subject of a future hearing, would not apply to the Dalkon Shield cases, as the product was sold without FDA approval, with evidence of concealed information by the manufacturer about the product's safety.

The fact of the matter is that suppliers of any raw materials typically do not have the ability to know about every end-use of their product. We do not expect Elmer's to stand in every hobby shop to ask customers how they plan on using its glue. Nor can we reasonably expect a biomaterials supplier to require their customers to provide samples of every product in which the supplies are to be used and then duplicate the manufacturers' testing and government approval requirements.

The vast majority of courts recognize the unreasonableness of such a burden. For example, DuPont has been sued 651 times over a single medical product for which they supplied raw materials. The company has now won 55 consecutive cases without liability. But it had to spend over $8 million annually in litigation to obtain the dismissals. And this does not include all of the employee time and resources taken away from other tasks, such as research and development. DuPont is a company with strong humanitarian interests and community involvement. But to ask it to continue supplying materials which might result for a single product in $8 million annual expenses and only a few hundred thousand in total revenue is simply unconscionable.

This is a real crisis. I don't want little Titus to have to go overseas for quality health care. I don't want Ms. Bergman to have to suffer more pain because a good knee joint replacement will no longer be available. And I refuse to continue placing at risk the health of so many other Americans who rely on medical implants containing potentially unavailable biomaterials. Such as Scott Jordan, who would be deaf without his biomaterial-using hearing device, or Frances de Monterey whose silastic joint implants give him full use his hands, or Carlos Medina whose heart attachment lets him fight off a deadly virus, or even Seth from Texas who uses a nerve stimulator to help control his epileptic seizures.

I am committed to using this hearing as the taking-off point for addressing the concerns of these real Americans, and ensuring that biomaterials supplies will be available in the future. This is a problem with a solution in hand, and one that I hope we can convince the President to sign this year.

G:\TTCP\PL\TAUZIN.STM